CLAIMS

1. A preparation comprising a β-amyloid variant or an N-terminal fragment thereof characterized in that said β-amyloid variant or said N-terminal fragment thereof contains an N-terminal truncation and/or a post-translational modification.

2. The preparation according to claim 1, further characterized in that the N-terminal truncated β-amyloid variant or the N-terminal fragment thereof starts at position 2, 3, 4, 5, 6, 7, 8, 9 or 10 of β-amyloid and that the post-translational modification is a methylation or a pyroglutamylation.

3. The preparation according to claim 2, further characterized in that the pyroglutamylation is present at position 3 of an N-terminal truncated β-amyloid variant starting at position 3 of β-amyloid.

4. The preparation according to any of claims 1 to 3, further characterized in that the β-amyloid variant or the N-terminal fragment thereof comprises an amino acid sequence selected from the group consisting of SEQ ID NOs 1 to 165.

5. The preparation according to any of claims 1 to 4, further characterized in that the β-amyloid variant or the N-terminal fragment thereof contains an additional modification resulting in a separated spot of the β-amyloid variant or the N-terminal fragment thereof on two-dimensional gel electrophoresis compared to the spot obtained with the β-amyloid variant or the N-terminal fragment thereof without said additional modification.

6. A preparation comprising an N-terminal APP soluble fragment obtainable by secretase cleavage of APP, characterized in that the C-terminal end of said N-terminal APP soluble fragment consists of position 1, 1 to 2, 1 to 3, 1 to 4, 1 to 5, 1 to 6, 1 to 7, 1 to 8, or 1 to 9 of β-amyloid, or a preparation comprising a C-terminal fragment thereof.

7. The preparation according to claim 6, further characterized in that the N-terminal APP soluble fragment or the C-terminal fragment thereof comprises an amino acid sequence selected from the group consisting of SEQ ID NOs 1 to 6, 14 to 18, 27 to 30, 53 to 55, 66 to 67, 79, and 166 to 261.

8. A nucleic acid preparation comprising a nucleic acid sequence capable of encoding the β-amyloid variant or the N-terminal fragment thereof according to any of claims 1 to 5.

9. A nucleic acid preparation comprising a nucleic acid sequence capable of encoding the N-terminal APP soluble fragment or the C-terminal fragment thereof according to any of claims 6 or 7.

10. A method for the preparation of an antibody that specifically recognizes an N-terminal truncated and/or post-translationally modified β-amyloid variant, comprising the following steps:
   (a) Immunizing an animal with a preparation according to any of claims 1 to 5 or with the nucleic acid preparation according to claim 8;
   (b) Obtaining the antibodies generated by the immunization in step (a);
   (c) Screening the antibodies obtained in step (b) for their specific recognition of N-terminal truncated and/or post-translationally modified β-amyloid variants.

11. An antibody obtainable by the method according to claim 10.

12. A method for the preparation of an antibody that specifically recognizes an N-terminal APP soluble fragment according to any of claims 6 or 7, comprising the following steps:
   (a) Immunizing an animal with a preparation of N-terminal APP soluble fragment or a C-terminal fragment thereof according to any of claims 6 or 7 or with the nucleic acid preparation according to claim 9;
   (b) Obtaining the antibodies generated by the immunization in step (a);
   (c) Screening the antibodies obtained in step (b) for their specific recognition of an N-terminal APP soluble fragment according to any of claims 6 or 7.

13. An antibody obtainable by the method according to claim 12.

14. A vaccine composition or a therapeutic composition comprising a preparation according to any of claims 1 to 5, comprising an antibody according to claim 11, or comprising a nucleic acid preparation according to claim 8.

15. A preparation according to any of claims 1 to 5, an antibody according to claim 11, or a nucleic acid preparation according to claim 8 for use as a prophylactic vaccine for the prevention of a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease.

16. A preparation according to any of claims 1 to 5, an antibody according to claim 11, or a nucleic acid preparation according to claim 8 for use as a therapeutic for the treatment of a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease.

17. Use of a preparation according to any of claims 1 to 5, an antibody according to claim 11, or a nucleic acid preparation according to claim 8 for the manufacture of a prophylactic vaccine for the prevention of a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease.

18. Use of a preparation according to any of claims 1 to 5, an antibody according to claim 11, or a nucleic acid preparation according to claim 8 for the manufacture of a therapeutic for the treatment of a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease.

19. A method for the prevention and/or treatment, in a mammal, of a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, said method comprising the administration, to said mammal, of a vaccine composition or a therapeutic composition according to claim 14.

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20. A diagnostic or theranostic kit comprising a preparation according to any of claims 1 to 5, comprising a preparation according to any of claims 6 or 7, or comprising an antibody according to any of claims 11 or 13.

5   21. A preparation according to any of claims 1 to 5 for use as a diagnostic or theranostic for the measurement of the immune response induced in a mammal by vaccination or therapeutic application with respectively a vaccine composition or a therapeutic composition according to claim 14.

10   22. Use of a preparation according to any of claims 1 to 5 for the manufacture of a diagnostic or theranostic kit for the measurement of the immune response induced in a mammal by vaccination or therapeutic application with respectively a vaccine composition or a therapeutic composition according to claim 14.

15   23. A method for the measurement, in a mammal, of the immune response induced by vaccination or therapeutic application with respectively a vaccine composition or a therapeutic composition according to claim 14, said method comprising the following steps:

(a) Determining, in a sample obtained from said mammal, the amount of antibody
20   specific for a β-amyloid variant according to any of claims 1 to 5;

(b) Comparing the amount determined in step (a) with the amount of antibody specific for said β-amyloid variant present in the mammal before vaccination or therapeutic application with the vaccine or therapeutic composition according to claim 14;

25   (c) Concluding, from the comparison in step (b), whether the mammal is responding to the vaccination or therapy, an increased amount of antibody specific for said β-amyloid variant being an indication that the mammal is responding to the vaccination or therapy.

30   24. A preparation according to any of claims 1 to 5, an antibody according to claim 11 or 13, or a preparation according to any of claims 6 or 7 for use as a diagnostic or theranostic for determining, in a mammal, the susceptibility to a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, for

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determining, in a mammal, the risk of developing a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, for screening of the clearance of β-amyloid deposition in a mammal, or for predicting the level of β-amyloid burden in a mammal.

25. Use of a preparation according to any of claims 1 to 5, an antibody according to claim 11 or 13, or a preparation according to any of claims 6 or 7 for the manufacture of a diagnostic or theranostic kit for determining, in a mammal, the susceptibility to a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, for determining, in a mammal, the risk of developing a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, for screening of the clearance of β-amyloid deposition in a mammal, or for predicting the level of β-amyloid burden in a mammal.

26. A method for determining, in a mammal, the susceptibility to a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, for determining, in a mammal, the risk of developing a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, for screening of the clearance of β-amyloid deposition in a mammal, or for predicting the level of β-amyloid burden in a mammal, said method comprising the following steps:

(a) Determining, in said mammal, the amount of β-amyloid variant according to any of claims 1 to 5, the amount of N-terminal APP soluble fragment according to any of claims 6 or 7, or the amount of antibody specific for said β-amyloid variant or said APP soluble fragment;

(b) Comparing the amount determined in step (a) with the amount of said β-amyloid variant, said N-terminal APP soluble fragment, or said antibody in a control mammal;

(c) Concluding, from the comparison in step (b), whether the mammal is susceptible to a disease associated with β-amyloid formation and/or aggregation such as Alzheimer's disease, whether the mammal is at risk of developing a disease associated with β-amyloid formation and/or aggregation

such as Alzheimer's disease, whether the β-amyloid deposition in the mammal is cleared, or what the level of β-amyloid burden is in said mammal.

27. The method according to claim 26, further characterized in that the amount of β-amyloid variant, the amount of N-terminal APP soluble fragment or the amount of antibody specific for said β-amyloid variant or said N-terminal APP soluble fragment is determined on a tissue sample obtained from said mammal.

28. The method according to claim 27 for predicting the level of β-amyloid burden in a mammal, said method comprising the following steps:
    (a) Administration, to said mammal, of a vaccine composition or a therapeutic composition according to claim 14;
    (b) Determining, in a biological fluid sample obtained from said mammal, the amount of β-amyloid variant according to any of claims 1 to 5;
    (c) Comparing the amount determined in step (b) with the amount of said β-amyloid variant in a biological fluid sample obtained from a control mammal;
    (d) Concluding, from the comparison in step (c), what the level of β-amyloid burden is in said mammal.